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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,284	07/01/2004	Gunvor Ekman-Ordeberg	1291-0215PUS1	9113

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
MAIER, LEIGH C	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
07/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/500,284	EKMAN-ORDEBERG ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 3 and 7 have been canceled. Claims 1, 5, 6 and 11 have been amended. Claims 1, 2, 4-6 and 8-11 have been amended. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite a particular group of sulfated glycosaminoglycans, including "low molecular weight heparan and depolymerised heparan." This would appear to be a typographical error, wherein the correct sulfated glycosaminoglycans would be "low molecular weight heparin and depolymerised heparin." However, it is noted that in the dependent claim 5, the claim has been specifically amended to change "heparin" to "heparan," it must be concluded that "heparan" is indeed what Applicant intends. However, as noted, the species are described as "*sulfated* glycosaminoglycans," so it is not clear exactly what Applicant intends in reciting "heparan"—which must be a sulfated glycosaminoglycan—as a species that distinguishes it from

the species "heparan sulfate," also recited as a species in the group. For this reason, the claims are rendered vague and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims1, 5, 6 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

As noted above, claim 1 has been amended to recite a particular group of sulfated glycosaminoglycans, including "low molecular weight *heparan* and depolymerised *heparan*." The examiner does not find that this species, separate from "heparan sulfate" is described in the specification. In noting support for the amendments, Applicant cites (1) page 5, 2nd full paragraph; (2) page 6, 2nd full paragraph; and (3) page 6, 4th full paragraph. However, (1) describes the use of heparan sulfates and depolymerized heparan sulfates; (2) describes the use of dermatan sulfates depolymerized dermatan sulfates; and (3) describes the use of heparin and depolymerized heparin. The examiner finds nothing in these passages describing this recited sulfated glycosaminoglycan, heparan, as an entity distinct from heparan sulfate.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 6 and 10 are again rejected under 35 U.S.C. 102(b) as being anticipated by Greinacher et al (Br. J. Obst. Gyn., 2001).

Greinacher discloses the administration of Org 10172 (a combination of heparan sulfate, chondroitin sulfate and dermatan sulfate, or danaparoid) to a pregnant woman. See entire reference.

Applicant's arguments filed April 10, 2007 have been fully considered but they are not persuasive.

Applicant contends that the present inventors "have found that the administration of low molecular weight heparans to pregnant women in need of thrombosis prophylaxis surprisingly has resulted in a faster progress of labor and shorter delivery time." However, Greinacher has already done the same thing – administered glycosaminoglycans recited in the claims to a pregnant woman in need of antithrombotic therapy. The fact that the reference is silent regarding the inherent effect on labor and delivery does not negate anticipation with respect to the prevention aspect of the invention. See MPEP 2112 [R-3] II.

Applicant further contends that "the present invention is directed to women without any need of antithrombotic therapy, but having a problem with slow progress or arrest of labor at delivery." The examiner would note that the claims do not exclude women in need of antithrombotic therapy, nor are they limited to women having said problem with labor and delivery because they expressly recite prophylaxis.

Claim Rejections - 35 USC § 103

Claims 1-4, 6 and 8-10 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Laster (EP 1016410) in view of Einarsson (US 5,714,477)—claim 9 or Atad (US 4,976,692)—claim 8.

Laster teaches the administration of glycosaminoglycans, preferably LMW heparin, heparan or dermatan, for the treatment of pre-eclampsia. See, for example, paragraph [0042]. The reference does not exemplify the treatment of women. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to administer these products to treat pre-eclampsia with a reasonable expectation of success because it is suggested in the art.

Laster does not teach topical administration or the administration of glycosaminoglycans in combination with oxytocin.

Einarsson teaches as set forth above.

It is known that pre-eclampsia is one of the most common indication for labor induction, which it typically done by the administration of oxytocin. See Atad at page 5, lines 50-58.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer glycosaminoglycans as set forth above. It would be further obvious to administer the agents topically as taught by Einarsson for the advantages set forth above, with a reasonable expectation of success. It would be further obvious to administer the agents in combination with oxytocin because the need for labor induction is common in women with pre-eclampsia.

Again, the patient population that would be treated as suggested by the combination of references is fully encompassed by the population contemplated in the instant claims, and in following the suggestions of the art, one of ordinary skill would accomplish the method.

Applicant's arguments filed April 10, 2007 have been fully considered but they are not persuasive.

Applicant argues that there is not disclosure regarding improving the progress of labor or delivery in the references. With respect to the references drawn to the administration of glycosaminoglycans, the examiner agrees with this statement. Atad, on the other hand, clearly discusses induction of labor. However, Laster clearly teaches the administration to glycosaminoglycans to the same patient population – pregnant women – as required in the claims. In administering said agent, the method is accomplished.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
June 22, 2007